DEC 16 2004

K043258
Page 1 of 3

Attachment 4
510(k) Summary

Substantial Equivalence

In accordance with the requirements of 21 CFR § 807, this summary is formatted with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." and can be used to provide equivalence summary to anyone requesting it from the Agency.

Manufacturer Teleflex Medical Inc.
50 Plantation Drive
Tall Pines Park
Jaffrey, NH 03452

Contact Person Susan Kagan
Regulatory Affairs Specialist
Phone: (508) 677-6675
Fax: (888) 273-6897
e-mail: skagan@teleflexmedical.com

Date Prepared November 16, 2004

Device Information

Common Name:	Guidewire Introduction Safety Needle with Introducer
Proprietary Name:	Modified TFX Medical Safety Needle with Introducer
Classification Name:	Tube, Gastrointestinal and Accessories

Indications for Use

The Modified TFX Medical Safety Needle with Introducer is intended to be used for guidewire introduction during gastrointestinal procedures such as PEG (Percutaneous Endoscopic Gastrostomy), PEJ (Percutaneous Endoscopic Jejunostomy) or other endoscopic gastrointestinal procedures requiring placement of a guidewire.

Device Description

This Intended Use of the Modified Safety Needle with Introducer device is identical to the Modified TFX Medical Safety Needle with Introducer cleared by the FDA in K021034. In order to provide a more robust design, the material of construction has been changed from High Density Polyethylene to Polypropylene. An increase in the outer diameter has also been implemented to add additional rigidity to the cannula sheath.

The Modified TFX Medical Safety Needle with Introducer will continue to allow placement of guidewires ranging from 0.015" – 0.052". The variance in sizes and lengths is due to the specific procedure, physician preference and patient body type.

This product consists of the following two components:

1. Safety Needle (Needle with Passive Sharps Protection)- The Safety Needle, has the same blunter technology as the Bio-Plexus, Punctur-Guard Blood Collection needle (K895024).

2. Sheath Introducer- The functionality of the peelable, splitable introducer is identical to the existing introducer sold by TFX Medical, which was initially cleared under K920908 and subsequently cleared under K021034 to be used for guidewire introduction during gastrointestinal procedures.

   The sheath will also be made available in a non-peelable configuration.

Substantial Equivalence

The device is similar in intended use, design, and performance characteristics to the currently cleared Modified TFX Medical Safety Needle with Introducer cleared under K021034.

The determination of substantial equivalence for this device was based on a detailed device description, performance testing and conformance with voluntary performance standards, e.g. ANSI/AAMI/ISO 10993-1 Biological Evaluation of Medical Devices.

1. Identification of the legally marketed device to which the submitter claims equivalence:

The Modified TFX Medical Safety Needle with Introducer is substantially equivalent in design and materials to:

- The TFX Medical Introducer Needle – K851140
- The PUNCTUR-GUARD Blood Collection Needle of Bio-Plexus, Inc, for the activation mechanism - K895024
- The TFX Medical Safety Needle with Introducer – K000665
- The Modified TFX Medical Safety Needle with Introducer-K021034

2. Summary of Technological Characteristics:

The device is equivalent technologically to the devices mentioned on pages 2. The change in sheath material from High Density Polyethylene to Polypropylene, plus the inclusion of a non-peelable sheath configuration is the reason for this submission.

The new material for the cannula, Polypropylene, is in the same family, Olefins, as the current material of the cannula, High Density Polyethylene. Therefore they behave very similarly under processing conditions such as molding, sterilization and aging.

The only difference between the peelable and non-peelabe introducers is that the skiving operation, which allows for the splitting of the sheath, is not performed during manufacturing. Otherwise all characteristics are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2004

Ms. Susan Kagan
Regulatory Affairs Specialist
Teleflex Medical
50 Plantation Drive
Tall Pines Park
JAFFREY NH 03452

Re: K043258
Trade/Device Name: Modified TFX Medical Safety Needle with Introducer
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: November 16, 2004
Received: November 24, 2004

Dear Ms. Kagan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

TFX Medical
Special 510(k) Submission: Modified TFX Medical
Safety Needle with Introducer

November 16, 2004

Indications for Use

510(k) Number (if known): K 043258
Device Name: Modified TFX Medical Safety Needle with Introducer

Indications for Use:

Indications for Use:

The Modified TFX Medical Safety Needle with Introducer is intended to be used for guidewire introduction during gastrointestinal procedures such as PEG (Percutaneous Endoscopic Gastrostomy), PEJ (Percutaneous Endoscopic Jejunostomy) or other endoscopic gastrointestinal procedures requiring placement of a guidewire.

Prescription Use __X_____
(Part 21 CFR 801 Subpart D)

~~AND~~/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Confidential

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043258